CRUZ) was added as a cosponsor of amendment No. 584 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

#### AMENDMENT NO. 650

At the request of Ms. Murkowski, the name of the Senator from North Dakota (Mr. Hoeven) was added as a cosponsor of amendment No. 650 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

#### AMENDMENT NO. 694

At the request of Mrs. Capito, the name of the Senator from Vermont (Mr. Sanders) was added as a cosponsor of amendment No. 694 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

#### AMENDMENT NO. 699

At the request of Mr. Brown, the name of the Senator from California (Ms. Harris) was added as a cosponsor of amendment No. 699 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

### AMENDMENT NO. 702

At the request of Mr. Graham, the name of the Senator from North Dakota (Mr. Hoeven) was added as a cosponsor of amendment No. 702 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

#### AMENDMENT NO. 773

At the request of Mr. PERDUE, the name of the Senator from Connecticut (Mr. BLUMENTHAL) was added as a cosponsor of amendment No. 773 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel

strengths for such fiscal year, and for other purposes.

#### AMENDMENT NO. 789

At the request of Mr. Murphy, the name of the Senator from Texas (Mr. Cruz) was added as a cosponsor of amendment No. 789 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

#### AMENDMENT NO. 859

At the request of Mr. CRUZ, the name of the Senator from Tennessee (Mrs. BLACKBURN) was added as a cosponsor of amendment No. 859 intended to be proposed to S. 1790, an original bill to authorize appropriations for fiscal year 2020 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

# STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

#### By Mr. MERKLEY:

S. 1987. A bill to require the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. MERKLEY. Mr. President, the three most important words of our Constitution are the first three: "We the People." That is what our entire vision of our form of government is about.

There was a lot of discussion among the Founders about how we make sure we don't end up with the equivalent of a King here in the United States of America because with a King, you get a government by and for the King and the King's circle, the powerful circle at the top, rather than the people.

Unfortunately, that vision in America is being challenged—challenged because we have a fundamental concentration of power through dark money in campaigns and gerrymandering through voter suppression and intimidation. The result is a shredding of the vision of our Constitution.

We have a responsibility in the Senate to fix that, and that is why we should be considering the For the People Act that takes on gerrymandering, voter suppression, and dark money. If we want evidence of just exactly how corrupted the system has become, go no further than to look at drug companies gouging Americans on drug prices.

Today I am introducing the End Price Gouging for Medications Act to stop the pharmaceutical companies' greed and give Americans much needed relief.

The average American spends about \$1,000 per year on medication. That is

11 times what they spent in 1960. More than half of Americans take at least one prescription medication—about 60 percent of us. One-quarter of them say they or family members have not filled a prescription or have cut pills in half or have skipped doses because of the cost, and those costs just keep going right on up.

January through June 2018, there were price increases on 4,412 drugs and decreases on just 46. That is a ratio that approaches 100 to 1. For every 100 drugs that go up in price, 1 comes down a little. We are clearly failing to tackle this problem.

I hear it from my constituents back in Oregon. Bonnie Davis from Creswell, who is a senior citizen on a fixed income and has been diabetic for 30 years, was prescribed two new kinds of insulin in December: BYDUREON, which costs \$1,927 for a 3-month supply, and Lantus SoloSTAR, which costs \$1,952. She will pay more than \$5,000 out of pocket by the end of the year. In 1972, insulin cost just \$1.49 per vial. What an incredible difference on a product that has been around forever.

Her two adult children are living in Germany. They thought about coming back to the United States of America but decided not to for one simple reason: the cost of healthcare in the United States of America and specifically the cost of medications.

I come from Douglas County, a little timber county in Southern Oregon. Leslie Rogers comes from that county. She comes from Roseburg, a town where I went to first grade. Leslie shared his daughter Gloria's story at one of my townhalls. Gloria suffers from a rare genetic condition called West syndrome. She lives, therefore, in near constant fear of seizures and cystic fibrosis. It is treatable.

It is treatable with a drug called ACTH. It was invented in the 1950s. Previously, it cost \$40 a vial—\$40—but in 8 years, the cost has grown to \$45,000. Yes, you heard that right—from \$40 to \$45,000. That is more than a thousandfold increase.

The company that makes the drug bought the rights to and blocked a \$200 synthetic ACTH treatment used in Canada to prevent it from coming to the United States. They are making a lot of money by blocking a generic synthetic competitor.

Leslie Rogers says: "Hospitalization and treatment drove my family to the edge of bankruptcy, and my daughter was left tube fed and suction dependent due to treatment delays fighting with insurance over the drug price."

How would you feel if your daughter or your son were left in a situation of being tube fed and suction dependent because you couldn't afford the drug because the drug had increased in price 1,000 times?

The cost of another drug used to treat the disease, Vigabatrin, has also skyrocketed after makers saw what the first company was able to get away with. It cost about \$1,500 a month 3

years ago, and \$1,500 is a lot. How much does it cost today? It costs \$26,000 per month. That is roughly a twentyfold increase.

Leslie Rogers notes: "This price gouging has led to thousands of children since we first spoke to suffer the same fate as my daughter—severe brain damage, cerebral palsy, reliance on tube feedings, and many have died."

Let's be clear. Price gouging in America isn't just about the pocketbook; it is about health, and it is about life or death for many people.

This situation doesn't exist in other countries. The whole entire price regime is different. Let's take, as an example, HUMIRA, a common drug for rheumatoid arthritis. Here in the United States, it is about \$2,700 per dose. In the United Kingdom, it is \$1,362. Why does it cost twice that in the United States of America for this drug, this common drug? Then there is CRESTOR, which is used to treat high cholesterol? It is \$216 in the United States, and it is \$32 in France. Crudely, that is a sevenfold increase in the United States over France. Why do we pay seven times as much as the people in France? There is also HARVONI that is used to treat hepatitis C. It cost \$13,000 in Japan and \$30,000 in United States. That is three times as much. Why do we pay three times what they pay in Japan for this drug? There is also JANUVIA that is used to treat type 2 diabetes. It costs \$34 in Australia and \$331 in the United States of America—a tenfold increase. Why do we pay 10 times as much as people in Australia?

There is an answer to the question the question of why we pay so much for HUMIRA, for CRESTOR, for HARVONI, and for JANUVIA. Very simply, other governments negotiate the price: If you want to sell it in our country, we negotiate the price.

We don't. Now, what is the reason why we don't? Why don't we pick up and do for Americans what the Government of Australia does for Australians, or the Government of the United Kingdom does for its citizens, or the Government of France does for their citizens? Why don't we do it for our citizens-the same good work in negotiating the price that other governments do? What is wrong with our government? What is wrong with this Chamber?

It is corruption. It is the absolute corruption of money in campaigns.

So who are we serving here in this Chamber? Are we serving the people or are we serving the drug companies? That is the question every Member of this Chamber should struggle with.

In the United States, drug companies set the price, and we don't negotiate. In fact, the U.S. Government has set a law saying the U.S. Government can't negotiate. Why would we do that? Why would we do that to ourselves? Why would we do that to the people of this country who cannot afford the drugs because we make them far more expensive than anywhere else in the world?

Well, we shouldn't. That is why I have introduced the End Price Gouging for Medications Act. On behalf of the people of America, we need to end the drug gouging.

Now, I do a lot of townhalls. I do one in every county every year. There are 36 counties in Oregon. It is open hour for people to ask questions. They are blue counties, and they are red counties. Twenty-two of my 36 are about as red as the reddest counties you will find in America.

I ask the people: How many people here at this townhall like getting gouged on drugs? Nobody does. How many people like paying 2 or 5 or 10 times more than the citizens of other developed countries? No one likes it.

America is united—rural America, urban America, blue America, red America, young America, old America. America is united to end this drug gouging.

So why don't we act?

I challenge my colleagues: Come here and work for the people of the United States of America rather than the drug companies' profits. It is time to stand up. Stand up against those companies.

This plan is quite simple. It says you can't sell the drug for more than the median price of what you sell it for in Australia, Japan, Canada, and the largest European countries. It is that simple. Median price in those markets. If you want to raise your prices in America, you have to raise your prices in those countries. That way we all get a fair deal. This would stop the drug gouging of Americans overnight.

This is quite simple, but you may ask how is it enforced? How do you make

sure that this happens? Well, it is this. The difference be-

tween the reference price, or the median price in those countries, and the price the drug company sells their product at-if they sell it for more than the median price, the penalty is five times the difference. If they sell it for \$1,000 more per dose over the median price, the penalty is \$5,000. That gets people's attention. Drug companies don't want to be paying massive penalties.

And where do the fines go? They go to the NIH for drug research and development. There is all this myth that we are not going to invest in drug development. The basic science is done by NIH, and this would fund NIH.

Americans have been ripped off. Americans have been gouged, and it is this Chamber that is allowing it to happen. Who here wants to come and say they are for the drug gouging of Americans?

Well, I can tell you that America is not with you if you are supporting the drug gouging of our citizens. So let's have the courage to carry the fight for the people, not the powerful.

> By Mr. DURBIN (for himself, Mr. BLUMENTHAL, Mrs. FEINSTEIN, and Mrs. GILLIBRAND):

S. 1995. A bill to establish the Food Safety Administration to protect the

public health by preventing foodborne illness, ensuring the safety of food, improving research on contaminants leading to foodborne illness and the chronic health outcomes associated with foodborne illnesses, improving the surveillance of foodborne pathogens (including foodborne pathogens identified as antibiotic resistant), and improving security of food from intentional contamination, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

Mr. DURBIN. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

#### S. 1995

Be it enacted by the Senate and House of Renresentatives of the United States of America in Congress assembled.

#### SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- (a) SHORT TITLE.—This Act may be cited as the "Safe Food Act of 2019"
- (b) Table of Contents.—The table of contents of this Act is as follows:
- Sec. 1. Short title; table of contents.
- Sec. 2. Findings; purposes.

Sec. 3. Definitions.

#### TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

- Sec. 101. Establishment of Food Safety Administration
- Sec. 102. Consolidation of separate food safety and inspection services and agencies
- Sec. 103. Additional duties of the Administration

#### TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

- Sec. 201. Administration of national program.
- Sec. 202. Registration of food facilities.
- Sec. 203. Preventive process controls to reduce adulteration of food.
- Sec. 204. Performance standards for contaminants in food.
- Sec. 205. Inspections of food facilities.
- Sec. 206. Food production establishments.
- Sec. 207. Federal and State cooperation.
- Sec. 208. Foreign supplier verification pro-
- gram. Sec. 209. Imports.
- Sec. 210. Traceback.
- Sec. 211. Food safety technology.
- TITLE III—RESEARCH AND EDUCATION
- Sec. 301. Public health assessment system.
- Sec. 302. Public education and advisory sys-
- Sec. 303. Research.

## TITLE IV—ENFORCEMENT

- Sec. 401. Prohibited acts.
- Sec. 402. Mandatory recall authority.
- Sec. 403. Injunction proceedings. Sec. 404. Civil and criminal penalties.
- Sec. 405. Presumption.
- Sec. 406. Whistleblower protection.
- Sec. 407. Administration and enforcement.
- Sec. 408. Citizen civil actions.

## TITLE V—IMPLEMENTATION

- Sec. 501. Definition.
- Sec. 502. Reorganization plan.
- Sec. 503. Transitional authorities.
- Sec. 504. Savings provisions.
- Sec. 505. Conforming amendments.
- Sec. 506. Additional technical and conforming amendments.
- Sec. 507. Regulations.
- Sec. 508. Authorization of appropriations.
- Sec. 509. Limitation on authorization of appropriations.

#### SEC. 2. FINDINGS: PURPOSES.

- (a) FINDINGS.—Congress finds that—
- (1) the safety of the food supply of the United States is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy:
- (2) lapses in the protection of the food supply and loss of public confidence in food safety are damaging to consumers and the food industry, and place a burden on interstate commerce:
- (3) the safety and security of the food supply requires an integrated, systemwide approach to preventing foodborne illness, a thorough and broad-based approach to basic and applied research, and intensive, effective, and efficient management of the Nation's food safety program;
- (4) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—
- (A) emerging pathogens and other contaminants and the ability to detect all forms of contamination;
- (B) an aging and immune-compromised population, with a growing number of people at high risk for foodborne illnesses, including infants and children;
- (C) a concern regarding food fraud for economic gain, especially with mislabeling and intentionally misleading claims:
- (D) an increasing volume of imported food, without adequate monitoring and inspection; and
- (E) maintenance of rigorous inspection of the domestic food processing and food service industries:
- (5) Federal food safety standard setting, inspection, enforcement, and research efforts should be based on the best available science and public health considerations and food safety resources should be systematically deployed in ways that most effectively prevent foodborne illness:
- (6) the Federal food safety system is fragmented, with at least 15 Federal agencies sharing responsibility for food safety, and operates under laws that do not reflect current conditions in the food system or current scientific knowledge about the cause and prevention of foodborne illness;
- (7) the fragmented Federal food safety system and outdated laws preclude an integrated, systemwide approach to preventing foodborne illness, to the effective and efficient operation of the Nation's food safety program, and to the most beneficial deployment of food safety resources;
- (8) the National Academy of Sciences recommended in the report "Ensuring Safe Food from Production to Consumption" that Congress establish by statute a unified and central framework for managing Federal food safety programs, and recommended modifying Federal statutes so that inspection, enforcement, and research efforts are based on scientifically supportable assessments of risks to public health; and
- (9) the lack of a single focal point for food safety leadership in the United States undercuts the ability of the United States to exert food safety leadership internationally, which is detrimental to the public health and the international trade interests of the United States.
- (b) Purposes.—The purposes of this Act are—
- (1) to establish a single agency to be known as the "Food Safety Administration"
- (A) regulate food safety and related labeling to strengthen the protection of the public health;
- (B) ensure that food facilities fulfill their responsibility to produce food in a manner that protects the public health of all people in the United States;

- (C) lead an integrated, systemwide approach to food safety and to make more effective and efficient use of resources to prevent foodborne illness;
- (D) provide a single focal point for food safety leadership, both nationally and internationally; and
- (E) provide an integrated food safety research capability, utilizing internally generated, scientifically and statistically valid studies or other food safety initiatives, in cooperation with academic institutions, food safety nonprofit organizations, and other scientific entities of the Federal and State governments, to achieve the continuous improvement of research on foodborne illness and contaminants;
- (2) to transfer to the Food Safety Administration the food safety, labeling, inspection, and enforcement functions that, as of the day before the date of enactment of this Act, are performed by other Federal agencies: and
- (3) to modernize and strengthen the Federal food safety laws to achieve more effective application and efficient management of the laws for the protection and improvement of public health.

#### SEC. 3. DEFINITIONS.

- In this Act:
- (1) ADMINISTRATION.—The term "Administration" means the Food Safety Administration established under section 101(a)(1).
- (2) ADMINISTRATOR.—The term "Administrator" means the Administrator of Food Safety appointed under section 101(a)(3).
  - (3) Adulterated.—
- (A) IN GENERAL.—The term "adulterated" has the meaning given the term in—
- (i) section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) for food regulated under such Act;
- (ii) section 1(m) of the Federal Meat Inspection Act (21 U.S.C. 601(m)) for food regulated under such Act;
- (iii) section 4(g) of the Poultry Products Inspection Act (21 U.S.C. 453(g)) for food regulated under such Act; and
- (iv) section 4(a) of the Egg Products Inspection Act (21 U.S.C. 1033(a)) for food regulated under such Act.
- (B) INCLUSION.—In applying the definitions cited in subparagraph (A), poisonous or deleterious substances in food shall be treated as an added substance if the poisonous or deleterious substances are known to cause serious illness or death in persons, including in sensitive populations.
- (4) AGENCY.—The term "agency" has the meaning given the term in section 551 of title 5, United States Code.
- (5) CATEGORY 1 FOOD FACILITY.—The term "category 1 food facility" means a facility that slaughters animals for food.
- (6) CATEGORY 2 FOOD FACILITY.—The term "category 2 food facility" means a facility that processes—
- (A) raw meat, poultry, or seafood in a manner that may reduce but is not validated to destroy contaminants; or
- (B) other products that the Administrator determines by regulation to be at high risk of contamination.
- (7) CATEGORY 3 FOOD FACILITY.—The term "category 3 food facility" means a facility—
- (A) that processes meat, poultry, or seafood, or other products that the Administrator determines by regulation to be at high risk of contamination; and
- (B) whose processes include one or more steps validated to destroy contaminants.
- (8) CATEGORY 4 FOOD FACILITY.—The term "category 4 food facility" means a facility that processes food but is not a category 1, 2, or 3 food facility.
- (9) CATEGORY 5 FOOD FACILITY.—The term "category 5 food facility" means a facility that stores, holds, or transports food prior to delivery for retail sale.

- (10) CONTAMINANT.—The term "contaminant" includes biological, chemical, physical, or radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food or color additives.
- (11) CONTAMINATION.—The term "contamination" refers to a presence of a contaminant in food, which may occur naturally or be introduced into a food.
- (12) FEED FACILITY.—The term "feed facility" means a domestic or foreign feed manufacturer, processor, packer, warehouse, or other facility that—
- (A) if operating in the United States, manufactures, slaughters, processes, or holds animal feed or feed ingredients; or
- (B) if operating elsewhere, manufactures, slaughters, processes, or holds animal feed or feed ingredients intended for consumption in the United States.
  - (13) FOOD.—
- (A) IN GENERAL.—The term "food" means a product intended to be used for food or drink for a human or an animal.
- (B) INCLUSIONS.—The term "food" includes any product (including a meat food product, as defined in section 1(j) of the Federal Meat Inspection Act (21 U.S.C. 601(j))), capable for use as human and animal food that is made in whole or in part from any animal, including cattle, sheep, swine, goat, or poultry (as defined in section 4 of the Poultry Products Inspection Act (21 U.S.C. 453)), and animal feed.
  - (14) FOOD FACILITY.—
- (A) IN GENERAL.—The term "food facility" means a domestic or foreign food manufacturer, slaughterhouse, processor, packer, warehouse, or other facility that—
- (i) if operating in the United States, manufactures, slaughters, processes, or holds food or food ingredients; or
- (ii) if operating outside the United States, manufactures, slaughters, processes, or holds food intended for consumption in the United States.
- (B) EXCLUSIONS.—For the purposes of registration, the term "food facility" does not include—
- (i) a farm, restaurant, other retail food establishment, nonprofit food establishment in which food is prepared for or served directly to the consumer; or
- (ii) a fishing vessel (other than a fishing vessel engaged in processing, as that term is defined in section 123.3(k) of title 21, Code of Federal Regulations).
- (15) FOOD PRODUCTION ESTABLISHMENT.—The term "food production establishment" means any farm, ranch, orchard, vineyard, aquaculture facility, or confined animal-feeding operation.
- (16) FOOD SAFETY LAW.—The term "food safety law" means—
- (A) the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) related to and requiring the safety, labeling, and inspection of food, infant formulas, food additives, pesticide residues, and other substances present in food under that Act;
- (B) the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and of any other Act that are administered by the Center for Veterinary Medicine of the Food and Drug Administration;
- (C) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);
- (D) the Federal Meat Inspection Act (21  $U.S.C.\ 601$  et seq.);
- (E) the FDA Food Safety Modernization Act (Public Law 111–353; 124 Stat. 3885);
- (F) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);
- (G) chapter 57 of title 49, United States Code (formerly known as the "Sanitary Food Transportation Act of 1990");

- (H) Public Law 85–765 (commonly known as the "Humane Methods of Slaughter Act of 1958") (7 U.S.C. 1901 et seq.);
  - (I) this Act; and
- (J) such other provisions of law related to and requiring food safety, labeling, inspection, and enforcement as the President designates by Executive order as appropriate to include within the jurisdiction of the Administration.
- (17) INTERSTATE COMMERCE.—The term "interstate commerce" has the meaning given the term in section 201(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(b)).
- (18) MISBRANDED.—The term "misbranded" has the meaning given the term in—
- (A) section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) for food regulated under such Act:
- (B) section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)) for food regulated under such Act:
- (C) section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)) for food regulated under such Act; and
- (D) section 4(l) of the Egg Products Inspection Act (21 U.S.C. 1033(l)) for food regulated under such Act.
- (19) PROCESS.—The term "process" or "processing" means the commercial slaughter, packing, preparation, or manufacture of food.
- (20) SAFE.—The term "safe" refers to human and animal health.
  - (21) STATE.—The term "State" means—
  - (A) a State:
  - (B) the District of Columbia;
- (C) the Commonwealth of Puerto Rico; and (D) any other territory or possession of the
- United States.

  (22) VALIDATION.—The term "validation" means the act of obtaining evidence that the process control measure or measures selected to control a contaminant in food is capable of effectively and consistently controlling the contaminant.
- (23) STATISTICALLY VALID.—The term "statistically valid" means evaluated and conducted under standards set by the National Institute of Standards and Technology.

# TITLE I—ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION

# SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRATION.

- (a) Establishment.—
- (1) IN GENERAL.—There is established in the Executive branch an agency to be known as the "Food Safety Administration".
- (2) STATUS.—The Administration shall be an independent establishment (as defined in section 104 of title 5, United States Code).
- (3) HEAD OF ADMINISTRATION.—The Administration shall be headed by the Administrator of Food Safety, who shall be appointed by the President, by and with the advice and consent of the Senate.
- (b) DUTIES OF ADMINISTRATOR.—The Administrator shall—
- (1) administer and enforce the food safety law;
- (2) serve as a representative to international food safety bodies and discussions;
- (3) promulgate regulations to ensure the security of the food supply from all forms of contamination, including intentional contamination; and
  - (4) oversee—
- (A) implementation of Federal food safety inspection, labeling, enforcement, and research efforts to protect the public health;
- (B) development of consistent and sciencebased standards for safe food;
- (C) coordination and prioritization of food safety research and education programs with other Federal agencies;
- (D) prioritization of Federal food safety efforts and deployment of Federal food safety

- resources to achieve the greatest benefit in reducing foodborne illness;
- (E) coordination of the Federal response to foodborne illness outbreaks with other Federal and State agencies; and
- (F) integration of Federal food safety activities with State and local agencies.

# SEC. 102. CONSOLIDATION OF SEPARATE FOOD SAFETY AND INSPECTION SERVICES AND AGENCIES.

- (a) Transfer of Functions.—For each Federal agency specified in subsection (b), there are transferred to the Administration all functions that the head of the Federal agency exercised on the day before the date of enactment of this Act (including all related functions of any officer or employee of the Federal agency) that relate to administration or enforcement of the food safety law, as determined by the President.
- (b) TRANSFERRED AGENCIES.—The Federal agencies referred to in subsection (a) are—
- (1) the Food Safety and Inspection Service of the Department of Agriculture;
- (2) the Center for Food Safety and Applied Nutrition of the Food and Drug Administration:
- (3) the part of the Agriculture Marketing Service that administers shell egg surveillance services established under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);
- (4) the resources and facilities of the Office of Regulatory Affairs of the Food and Drug Administration that administer and conduct inspections of food and feed facilities and imports;
- (5) the Center for Veterinary Medicine of the Food and Drug Administration;
- (6) the Office of Food Policy and Response of the Food and Drug Administration;
- (7) the part of the Research, Education, and Economics mission area of the Department of Agriculture related to food and feed safety:
- (8) the part of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration of the Department of Commerce that administers the seafood inspection program;
- (9) the part of the Animal and Plant Inspection Health Service of the Department of Agriculture related to the management of animals going into the food supply; and
- (10) such other offices, services, or agencies as the President designates by Executive order to carry out this Act.

# SEC. 103. ADDITIONAL DUTIES OF THE ADMINISTRATION.

- (a) OFFICERS AND EMPLOYEES.—The Administrator may—  $\,$
- (1) appoint officers and employees for the Administration in accordance with the provisions of title 5, United States Code, relating to appointment in the competitive service; and
- (2) fix the compensation of those officers and employees in accordance with chapter 51 and with subchapter III of chapter 53 of that title, relating to classification and General Schedule pay rates.
- (b) EXPERTS AND CONSULTANTS.—The Administrator may—
- (1) procure the services of temporary or intermittent experts and consultants as authorized by section 3109 of title 5, United States Code; and
- (2) pay in connection with those services the travel expenses of the experts and consultants, including transportation and per diem in lieu of subsistence while away from the homes or regular places of business of the individuals, as authorized by section 5703 of that title.
- (c) Bureaus, Offices, and Divisions.—The Administrator may establish within the Administration such bureaus, offices, and divisions as the Administrator determines are

- necessary to perform the duties of the Administrator.
  - (d) ADVISORY COMMITTEES.—
- (1) IN GENERAL.—The Administrator shall establish advisory committees that consist of representatives of scientific expert bodies, academics, industry specialists, and consumers.
- (2) DUTIES.—The duties of an advisory committee established under paragraph (1) may include developing recommendations with respect to the development of regulatory science and processes, research, communications, performance standards, and inspection.

# TITLE II—ADMINISTRATION OF FOOD SAFETY PROGRAM

# SEC. 201. ADMINISTRATION OF NATIONAL PROGRAM.

- (a) IN GENERAL.—The Administrator shall—
- (1) administer a national food safety program (referred to in this section as the "program") to protect public health; and
- (2) ensure that persons who produce or process food meet their responsibility to prevent or minimize food safety hazards related to their products.
- (b) COMPREHENSIVE ANALYSIS.—The program shall be based on a comprehensive analysis of the hazards associated with different food and with the processing of different food, including the identification and evaluation of—
  - (1) the severity of the health risks;
- (2) the sources and specific points of potential contamination extending from the farm or ranch to the consumer that may render food unsafe;
- (3) the potential for persistence, multiplication, or concentration of naturally occurring or added contaminants in food:
- (4) opportunities across the food production, processing, distribution, and retail system to manage and reduce potential health risks; and
- (5) opportunities for intentional contamination.
- (c) Program Elements.—In carrying out the program, the Administrator shall—  $\,$
- (1) adopt and implement a national system for the registration of food facilities and regular unannounced inspection of food facilities:
- (2) verify and enforce the adoption of preventive process controls in food facilities, based on the best available scientific and public health considerations and best available technologies;
- (3) establish and enforce science-based standards for—
- (A) substances that may contaminate food; and
- (B) safety and sanitation in the processing and handling of food:
- (4) implement a statistically valid sampling program to ensure that industry programs and procedures that prevent food contamination are effective on an ongoing basis and that food meets the performance standards established under this Act;
- (5) implement procedures and requirements to ensure the safety and security of imported food:
- (6) coordinate with other agencies and State or local governments in carrying out inspection, enforcement, research, and monitoring:
- (7) access the surveillance data of the Centers for Disease Control and Prevention, and other Federal Government agencies, in order to develop and implement a national surveillance system to assess the health risks associated with the human consumption of food or to create surveillance data and studies to mitigate food threats (such as antibiotic resistance) or to identify the ways that food

- contamination spreads through environ-
- (8) partner with relevant agencies to identify and prevent terrorist threats to food;
- (9) establish a process for providing a single point of contact to assist impacted consumers in navigating Federal, State, and local agencies involved in responding to or monitoring a foodborne outbreak;
- (10) develop public education risk communication and advisory programs;
- (11) implement a basic and applied research program to further the purposes of this Act; and
- (12) coordinate and prioritize food safety research and educational programs with other agencies, including State or local agencies.

#### SEC. 202. REGISTRATION OF FOOD FACILITIES.

- (a) IN GENERAL.—The Administrator shall require that all food and feed facilities register before the facility can operate in the United States or import food, feed, or ingredients into the United States.
  - (b) REGISTRATION REQUIREMENTS.
- (1) IN GENERAL.—To be registered under subsection (a)-
- (A) all food facilities covered under this Act shall comply with registration requirements in section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d);
- (B) for food facilities that have not registered under such section 415 prior to the date of enactment of this Act, the requirement in subparagraph (A) applies beginning on the day that is 180 days after the date of enactment of this Act: and
- (C) for food facilities that have registered under such section 415 prior to the date of enactment of this Act, such facilities shall file an amended registration within 180 days of such date of enactment to deliver the information required by paragraph (2).
- (2) Categories.—In addition to the information required under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) to be included in registration, a food facility shall-
- (A) list the facility's primary purpose and business activity, including the dates of operation if the food facility is operating seasonally; and
- (B) list the types of food handled at the facility and identify the activities conducted in the facility, that are relevant to determining whether the facility is a category 1, 2, 3, 4, or 5 facility.
- (3) PROCEDURE.—Upon receipt of a completed or amended registration described in paragraph (1), the Administrator shall notify the registrant of the receipt of the registration, review the activities identified in the registration, designate the facility as a category 1, 2, 3, 4, or 5 food facility for the purposes of inspection, and assign a registration number to each food facility.
- (4) LIST.—The Administrator-
- (A) shall compile and maintain an up-todate list of food facilities that are registered under this section, in accordance with section 415(a)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(a)(5)); and
- (B) may establish regulations on how the list may be shared with other governmental authorities.

#### SEC. 203. PREVENTIVE PROCESS CONTROLS TO REDUCE ADULTERATION OF FOOD.

- (a) IN GENERAL.—The Administrator shall review existing regulations on hazard analysis and process controls and amend existing regulations as appropriate, upon the basis of best available public health, scientific, and technological information, to ensure that those regulations are working effectively to-
- (1) ensure food facilities operate in a sanitary manner so that food is not adulterated;

- (2) limit the presence of contaminants in food;
- (3) meet the performance standards established under section 204;
- (4) ensure fully processed or ready-to-eat foods are processed using reasonably available techniques and technologies to eliminate contaminants;
- (5) label food intended for final processing outside commercial food facilities with instructions for handling and preparation for consumption that will destroy contaminants:
- (6) require sampling and testing at a frequency and in a manner sufficient to ensure that process controls are effective on an ongoing basis and that performance standards are being met; and
- (7) provide for agency access to records kept by food facilities and submission of copies of the records to the Administrator, as the Administrator determines appropriate.
- (b) PROCESSING CONTROLS.—The Administrator may require any person with responsibility for or control over food or food ingredients to adopt process controls, if the process controls are needed to ensure the protection of the public health.

#### SEC. 204. PERFORMANCE STANDARDS FOR CON-TAMINANTS IN FOOD.

- (a) PERFORMANCE STANDARDS.—Whenever Administrator determines that foodborne contaminant presents the risk of serious adverse health consequences or death to consumers, causes food to be adulterated, or could promote the spread of communicable disease described in section 361 of the Public Health Service Act (42 U.S.C. 264), the Administrator shall issue a performance standard (in the form of guidance, action levels, or regulations) to prevent or control the contaminant
  - (b) Enforcement.-
- (1) IN GENERAL.—Not later than 1 year after the promulgation of a performance standard under this section, the Administrator shall implement a statistically significant sampling program to determine whether food facilities are complying with the standards promulgated under this section.
- (2) ACTIONS.—If the Administrator determines that a food facility fails to meet a standard promulgated under this section, and such facility fails to take appropriate corrective action as determined by the Administrator, the Administrator shall, as appropriate-
- (A) detain, seize, or condemn food from the food facility under section 209(i);
- (B) order a recall of food from the food facility under section 402;
- (C) increase the inspection frequency for the food facility;
- (D) withdraw the mark of inspection from the food facility, if in use; or
- (E) take other appropriate enforcement action concerning the food facility, including suspension of registration.
- (c) NEWLY IDENTIFIED CONTAMINANTS.—Notwithstanding any other provision of this section, the Administrator shall promulgate interim performance standards for newly identified contaminants as necessary to protect the public health.
- (d) REVOCATION BY ADMINISTRATOR.—All performance standards, tolerances, action levels, or other similar standards with respect to food in effect on the date of enactment of this Act shall remain in effect until revised or revoked by the Administrator.

### SEC. 205. INSPECTIONS OF FOOD FACILITIES.

- (a) IN GENERAL.—The Administrator shall establish an inspection program, which shall include sampling and testing of food and food facilities, to determine if each food facility
- (1) is operating in a sanitary manner;
- (2) has continuous systems, interventions, and processes in place to minimize or eliminate contaminants in food;

- (3) uses validated process controls and ongoing verification;
- (4) is in compliance with applicable performance standards established under section 204, process control regulations, and other requirements:
- (5) is processing food that is safe and not adulterated or misbranded;
- (6) maintains records of process control plans under section 203, and other records related to the processing, sampling, and handling of food; and
- (7) is in compliance with the requirements of the applicable food safety law.
- (b) FACILITY CATEGORIES AND INSPECTION FREQUENCIES.—Inspections of food facilities under this Act shall be based on the following categories and inspection frequencies, subject to subsections (c), (d), and (e):
- (1) CATEGORY 1 FOOD FACILITIES.—A category 1 food facility shall be subject to antemortem, postmortem, and continuous inspection of each slaughter line during all operating hours, and other inspection on a daily basis, sufficient to verify that-
- (A) diseased animals are not offered for slaughter:
- (B) the food facility has successfully identified and removed from the slaughter line visibly defective or contaminated carcasses. has avoided cross-contamination, and has destroyed or reprocessed contaminated carcasses in a manner acceptable to the Administrator: and
- (C) applicable performance standards and other provisions of the food safety law, including those intended to eliminate or reduce pathogens, have been satisfied.
- (2) CATEGORY 2 FOOD FACILITIES.egory 2 food facility shall be randomly inspected at least daily.
- (3) CATEGORY 3 FOOD FACILITIES.—A category 3 food facility shall-
- (A) provide documentation to the Administrator on request that ongoing verification shows that its processes are controlled; and
- (B) be randomly inspected at least monthly.
- (4) CATEGORY 4 FOOD FACILITIES.—A category 4 food facility shall be randomly inspected at least quarterly.
- (5) CATEGORY 5 FOOD FACILITIES.—A category 5 food facility shall be randomly inspected at least annually.
- (c) Establishment of Inspection Proce-DURES.—The Administrator shall establish procedures under which inspectors or safety officers inspect food facilities, which shall allow the taking of random samples, photographs, and copies of records in food facilities.
- (d) ALTERNATIVE INSPECTION FRE-QUENCIES.-
- (1) IN GENERAL.—With respect to a category 2, 3, 4, or 5 food facility, to foster a riskbased allocation of resources, the Administrator may establish, in accordance with this subsection, alternative increased or decreased inspection frequencies for-
- (A) 1 or more subcategories of food facilities under paragraph (2); and
- (B) 1 or more specific food facilities under paragraph (3).
- (2) DETERMINATION OF SUBCATEGORIES AND FREQUENCIES .-
- (A) IN GENERAL.—The Administrator shall define, by regulation, each subcategory of food facilities established under paragraph (1)(A) and the alternative inspection frequency of that subcategory.
- (B) CONSIDERATIONS.—In defining a subcategory of food facilities and the alternative inspection frequency of that subcategory under subparagraph (A), the Administrator shall consider-
- (i) the nature of the foods being processed, stored, or transported;

- (ii) the manner in which foods are processed, stored, or transported;
- (iii) the inherent likelihood that the foods will contribute to the risk of foodborne illness;
- (iv) the best available evidence concerning reported illnesses associated with the foods produced in the proposed subcategory of facilities; and
- (v) the overall record of compliance with the food safety law among facilities in the proposed subcategory, including compliance with applicable performance standards and the frequency of recalls.
  - (3) Specific facilities.—
  - (A) IN GENERAL.—The Administrator—
- (i) may establish an alternative inspection frequency for increased or decreased inspection for a specific food facility; and
- (ii) shall annually publish a list of food facilities subject to alternative inspection frequencies under clause (i).
- (B) Considerations.—In establishing an alternative inspection frequency for a specific food facility, the Administrator shall consider—
- (i) the supporting evidence that the specific food facility shall submit to the Administrator relating to whether an alternative inspection frequency should be established for that facility by the Administrator:
- (ii) whether products from the specific food facility have been associated with a case or an outbreak of foodborne illness;
- (iii) the record of the facility of compliance with the food safety law, including compliance with applicable performance standards and the frequency of recalls; and
- (iv) the considerations described in clauses (i) through (iii) of paragraph (2)(B).
- (4) FREQUENCY REQUIREMENTS FOR CATEGORIES 2, 3, AND 4.—An alternative inspection frequency for a subcategory of food facilities or a specific food facility under this subsection shall be—
- (A) in the case of a category 2 food facility not less frequently than monthly; and
- (B) in the case of a category 3 or 4 food facility, not less frequently than annually.
- (5) REQUIREMENTS FOR DECREASED FRE-QUENCIES.—Before issuing a regulation or order establishing a decreased alternative inspection frequency for a subcategory of food facilities or an individual food facility under this subsection, the Administrator shall—
- (A) describe, in general terms, the alternative uses of resources of the Administration that would have been required to carry out the inspection activity; and
- (B) determine, based on the best available evidence, that the alternative uses of the resources would make a greater contribution to protecting the public health and reducing the risk of foodborne illness.
- (e) INSPECTION TRANSITION.—The Administrator shall manage the transition to the inspection system described in this Act as follows:
- (1) REGULATIONS.—The Administrator shall promulgate regulations to implement this section no later than 24 months after the date of enactment of this Act.
- (2) LIMIT ON REDUCTION IN INSPECTION FREQUENCY.—For any food facility, the Administrator shall not reduce the inspection frequency from the frequency required pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) until the food facility has demonstrated that sufficient changes in facilities, procedures, personnel, or other aspects of the process control system have been made such that the Administrator determines that compliance with the food safety law is achieved.
  - (f) OFFICIAL MARK.—

- (1) IN GENERAL.—
- (A) ESTABLISHMENT.—Before the completion of the transition process under subsection (e), the Administrator shall by regulation establish an official mark that can be affixed to a food produced in a category 1, 2, or 3 food facility if—
- (i) the facility is in compliance with the food safety law; and
- (ii) has been inspected in accordance with the inspection frequencies under this section.
- (B) REMOVAL OF OFFICIAL MARK.—The Administrator shall promulgate regulations that provide for the removal of the official mark under this subsection if—
- (i) the Administrator makes a finding that the facility is not in compliance with the food safety law; or
- (ii) the Administrator suspends the registration of the facility.
- (2) CATEGORY 1, 2, OR 3 FOOD FACILITIES.—In the case of products manufactured, slaughtered, processed, or held in a category 1, 2, or 3 food facility—
- (A) products subject to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as of the date of enactment of this Act shall remain subject to the requirement under those Acts that they bear the mark of inspection pending completion of the transition process under subsection (e):
- (B) the Administrator shall publicly certify on a monthly basis that the inspection frequencies required under this section have been achieved; and
- (C) a product from a facility that has not been inspected in accordance with the required frequencies under this section shall not bear the official mark and shall not be shipped in interstate commerce.
- (3) CATEGORY 4 AND 5 FOOD FACILITIES.—In the case of a product manufactured, slaughtered, processed, or held in a category 4 or 5 food facility, the Administrator shall provide by regulation for the voluntary use of the official mark established under paragraph (1), subject to—
- (A) such minimum inspection frequencies as determined appropriate by the Administrator;
- (B) compliance with applicable performance standards and other provisions of the food safety law; and
- (C) such other requirements as the Administrator considers appropriate.
- (g) MAINTENANCE AND INSPECTION OF RECORDS.—
- (1) IN GENERAL.—
- (A) RECORDS.—A food facility shall—
- (i) maintain such records as the Administrator requires by regulation, including all records relating to the processing, distributing, receipt, or importation of any food; and
- (ii) permit the Administrator, in addition to any authority of the food safety agencies in effect on the day before the date of enactment of this Act, upon presentation of appropriate credentials and at reasonable times and in a reasonable manner, to have access to and copy all records maintained by or on behalf of such food facility representative in any format (including paper or electronic) and at any location, that are necessary to assist the Administrator to determine whether the food is contaminated or not in compliance with the food safety law.
- (B) REQUIRED DISCLOSURE.—A food facility shall have an affirmative obligation to disclose to the Administrator the results of testing or sampling of food, equipment, or material in contact with food that is positive for any contaminant.

- (2) MAINTENANCE OF RECORDS.—The records required by paragraph (1) shall be maintained for a reasonable period of time, as determined by the Administrator.
- (3) REQUIREMENTS.—The records required by paragraph (1) shall include records describing—
- (A) the origin, receipt, delivery, sale, movement, holding, and disposition of food or ingredients;
- (B) the identity and quantity of ingredients used in the food;
  - (C) the processing of the food;
- (D) the results of laboratory, sanitation, or other tests performed on the food or in the food facility;
- (E) consumer complaints concerning the food or packaging of the food;
- (F) the production codes, open date codes, and locations of food production; and
- (G) other matters reasonably related to whether food is unsafe, is adulterated or misbranded, or otherwise fails to meet the requirements of this Act.
- (h) PROTECTION OF SENSITIVE INFORMATION —
- (1) IN GENERAL.—The Administrator shall develop and maintain procedures to prevent the unauthorized disclosure of any trade secret or confidential information obtained by the Administrator.
- (2) LIMITATION.—The requirement under this subsection does not—
- (A) limit the authority of the Administrator to inspect or copy records or to require the facility or maintenance of records under this Act;
- (B) have any legal effect on section 1905 of title 18, United States Code;
- (C) extend to any food recipe, financial data, pricing data, personnel data, or sales data (other than shipment dates relating to sales):
- (D) limit the public disclosure of distribution records or other records related to food subject to a voluntary or mandatory recall under section 402; or
- (E) limit the authority of the Administrator to promulgate regulations to permit the sharing of data with other governmental authorities.
- (i) BRIBERY OF OR GIFTS TO INSPECTOR OR OTHER OFFICERS AND ACCEPTANCE OF GIFTS.—Section 22 of the Federal Meat Inspection Act (21 U.S.C. 622) shall apply under this Act. SEC. 206. FOOD PRODUCTION ESTABLISHMENTS.
- In carrying out the duties of the Administrator and the purposes of this Act, the Administrator shall have the authority, with respect to food production establishments, to—
- (1) visit and inspect food production establishments in the United States and in foreign countries for food safety purposes;
- (2) review food safety records as needed to carry out traceback and for other food safety purposes;
- (3) set good practice standards to protect the public and promote food safety;
- (4) partner with appropriate agencies to monitor animals, plants, products, or the environment, as appropriate; and
- (5) collect and maintain information relevant to public health and farm practices. SEC. 207. FEDERAL AND STATE COOPERATION.
- (a) IN GENERAL.—The Administrator shall work with the States to carry out activities and programs that create a national food safety program so that Federal and State programs function in a coordinated and cost-effective manner.
- (b) STATE ACTION.—The Administrator shall work with States to—
- (1) continue, strengthen, or establish State food safety programs, especially with respect to the regulation of retail commercial food establishments, transportation, harvesting, and fresh markets;

- (2) continue, strengthen, or establish inspection programs and requirements to ensure that food under the jurisdiction of the State is safe; and
- (3) support recall authorities at the State and local levels.
- (c) ASSISTANCE.—To assist in planning, developing, and implementing a food safety program, the Administrator may provide to a State—
  - (1) advisory assistance;
- (2) technical and laboratory assistance and training (including necessary materials and equipment); and
- (3) financial assistance, in kind assistance, and other aid.
  - (d) SERVICE AGREEMENTS.—
- (1) IN GENERAL.—The Administrator may, under agreements entered into with Federal, State, or local agencies, use on a reimbursable basis or otherwise the personnel and services of those agencies in carrying out this Act.
- (2) TRAINING.—Agreements with a State under this subsection may provide for training of State employees.
- (3) MAINTENANCE OF AGREEMENTS.—The Administrator shall maintain any agreement that is in effect on the day before the date of enactment of this Act until the Administrator evaluates such agreement and determines whether to maintain or substitute such agreement.
- (e) AUDITS.-
- (1) IN GENERAL.—The Administrator shall annually conduct a comprehensive review of each State program that provides services to the Administrator in carrying out the responsibilities under this Act, including mandated inspections under section 205.
  - (2) REQUIREMENTS.—The review shall—
- (A) include a determination of the effectiveness of the State program; and
- (B) identify any changes necessary to ensure enforcement of Federal requirements under this Act.
- (f) No Federal Preemption.—Nothing in this Act shall be construed to preempt the enforcement of State food safety laws and standards that are at least as stringent as those under this Act.

# SEC. 208. FOREIGN SUPPLIER VERIFICATION PROGRAM.

- (a) IN GENERAL.—The Administrator shall require that each importer of products from a feed facility, food facility, or food producer establishment be in compliance with the foreign supplier verification program requirements under section 805 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384a).
- (b) RULE OF CONSTRUCTION.—In applying subsection (a) with respect to products subject to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), references in section 805 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384a) to sections 402, 403(w), 418, and 419 of such Act (21 U.S.C. 342, 343(w), 350g, and 350h) shall be construed to be references to the corresponding provisions of the food safety law, if any, that apply to such products, as determined by the Administrator.
- (c) REPEAL OF EXEMPTIONS.—Section 805 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384a) is amended—
- (1) in subsection (a)(1), by striking "subsections (e) and (f)" and inserting "subsection (e)":
  - (2) by striking subsection (e); and
- (3) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

#### SEC. 209. IMPORTS.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Administrator shall establish a system under

- which a foreign government seeking to certify food for importation into the United States shall submit a request for accreditation to the Administrator.
- (b) ACCREDITATION STANDARD.—A foreign government requesting to be accredited to certify food for importation into the United States shall demonstrate, in a manner determined appropriate by the Administrator, that the foreign government (or an agency thereof) is capable of adequately ensuring that eligible entities or foods certified by such government (or agency) meet the requirements of the food safety law.
- (c) REQUEST BY FOREIGN GOVERNMENT.—Prior to granting accreditation to a foreign government under this section, the Administrator shall review and audit the food safety program of the requesting foreign government and certify that such program (including all statutes, regulations, and inspection authority) meets the standard specified in subsection (b).
- (d) LIMITATIONS.—Any accreditation of a foreign government under this section shall—
- (1) specify the foods covered by the accreditation; and
- (2) be limited to a period not to exceed 5 years.
- (e) WITHDRAWAL OF ACCREDITATION.—The Administrator may withdraw accreditation fully or partially from a foreign government if the Administrator finds that.—
- (1) food covered by the accreditation is linked to an outbreak of human illness;
- (2) the programs or procedures of the foreign government no longer meet the standards of the food safety programs and procedures of the United States: or
- (3) the foreign government refuses to allow United States officials to conduct such audits and investigations as may be necessary to fulfill the requirements under this section.
- (f) RENEWAL OF ACCREDITATION.—The Administrator shall audit foreign governments accredited under this section at least every 5 years to ensure the continued compliance by such governments with the standard set forth in subsection (b).
- (g) REQUIRED ROUTINE INSPECTION.—The Administrator shall routinely inspect food or food animals by physical examination before the food or food animals enter the United States to ensure that the food or food animals—
- (1) are safe;
- (2) are labeled as required for food produced in the United States; and
- (3) otherwise meet the requirements of the food safety law.
- (h) ENFORCEMENT.—The Administrator may—
- (1) deny importation of food from any country if the country's government does not permit United States officials to enter the country to conduct such audits and inspections as may be necessary to fulfill the requirements under this section:
- (2) deny importation of food from any country or foreign facility that does not consent to an investigation by the Administrator when food from that country or foreign facility is linked to a foodborne illness outbreak or is otherwise found to be adulterated or mislabeled; and
- (3) promulgate regulations to carry out the purposes of this section, including setting terms and conditions for the destruction of products that fail to meet the standards of the food safety law.
- (i) DETENTION AND SEIZURE.—Any food imported for consumption in the United States that fails to meet the standards of the food safety law may be detained, seized, or condemned.

#### SEC. 210. TRACEBACK.

- (a) IN GENERAL.—The Administrator, in order to protect the public health, shall establish requirements for a national system for tracing food, animals, or ingredients from point of origin to retail sale, subject to subsection (b).
- (b) APPLICABILITY.—Traceability requirements shall—
- (1) be established in accordance with regulations and guidelines issued by the Administrator; and
- (2) apply to food production establishments and food facilities.

#### SEC. 211. FOOD SAFETY TECHNOLOGY.

- (a) IN GENERAL.—The Administrator shall establish and implement a program, to be known as the Food Safety Technology Program, to foster innovation in food technologies and foods that have the potential to improve food safety at the point of production, processing, transport, storage, or final preparation.
- (b) PROGRAM DESCRIBED.—The program under this section shall consist of technical guidance to and consultation with technology developers to assist them in meeting requirements for approval of technologies and products described in subsection (a).

# TITLE III—RESEARCH AND EDUCATION SEC. 301. PUBLIC HEALTH ASSESSMENT SYSTEM.

- (a) IN GENERAL.—The Administrator, acting in coordination with the Director of the Centers for Disease Control and Prevention and the Deputy Under Secretary of Agriculture for Research, Education, and Economics, shall—
- (1) have access to the applicable data systems of the Centers for Disease Control and Prevention and to the databases made available by a State;
- (2) partner with relevant agencies to maintain or access an active surveillance system of food and epidemiological evidence submitted by States to the Centers for Disease Control and Prevention based on a representative proportion of the population of the United States:
- (3) assess the frequency and sources of human illness in the United States associated with the consumption of food;
- (4) partner with relevant agencies to maintain or access a state-of-the-art partial or full genome sequencing system and epidemiological system dedicated to foodborne illness identification, outbreaks, and containment; and
- (5) have access to the surveillance data created via monitoring and statistical studies conducted as part of its own inspection.
  - (b) Public Health Sampling.—
- (1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Administrator shall establish guidelines for a sampling system under which the Administrator shall take and analyze samples of food—
- (A) to assist the Administrator in carrying out this Act; and
- (B) to assess the nature, frequency of occurrence, and quantities of contaminants in food.
- (2) REQUIREMENTS.—The sampling system described in paragraph (1) shall provide—  $\,$
- (A) statistically valid monitoring, including market-based studies, on the nature, frequency of occurrence, and quantities of contaminants in food available to consumers; and
- (B) at the request of the Administrator, such other information, including analysis of monitoring and verification samples, as the Administrator determines may be useful in assessing the occurrence of contaminants in food.
- (c) ASSESSMENT OF HEALTH HAZARDS.— Through the surveillance system referred to

in subsection (a), the sampling system described in subsection (b), and other available data, the Administrator shall—

- (1) rank food categories based on the hazard to human health presented by the food category;
- (2) identify appropriate industry and regulatory approaches to minimize hazards in the food supply; and
- (3) assess the public health environment for emerging diseases, including zoonosis, for their risk of appearance in the United States food supply.

# SEC. 302. PUBLIC EDUCATION AND ADVISORY SYSTEM.

- (a) PUBLIC EDUCATION.—The Administrator shall—
- (1) in cooperation with private and public organizations, including the cooperative extension services and building on the efforts of appropriate State and local entities, establish a national public education program on food safety; and
- (2) coordinate with other Federal departments and agencies to integrate food safety messaging into all food-related agricultural, nutrition, and health promotion programs.
- (b) HEALTH ADVISORIES.—The Administrator, in consultation with such other Federal departments and agencies as the Administrator determines necessary, shall work with the States and other appropriate entities—
- (1) to develop and distribute regional and national advisories concerning food safety;
- (2) to develop standardized formats for written and broadcast advisories;
- (3) to incorporate State and local advisories into the national public education program established under subsection (a); and
- (4) to present prompt, specific information regarding foods found to pose a threat to the public health.

#### SEC. 303. RESEARCH.

- (a) IN GENERAL.—The Administrator shall conduct research to carry out this Act, including studies to—
- (1) improve sanitation and food safety practices in the processing of food;
- (2) develop improved techniques to monitor and inspect food;
- (3) develop efficient, rapid, and sensitive methods to detect contaminants in food;
- (4) determine the sources of contamination of contaminated food;
- (5) develop food consumption data;
- (6) identify ways that animal production techniques could improve the safety of the food supply:
- (7) draw upon research and educational programs that exist at the State and local level;
- (8) determine the food safety education needs of vulnerable populations, including children less than 10 years of age, pregnant women, adults 65 years of age and older, and individuals with compromised immune sys-
- (9) utilize the partial or full genome sequencing system and other processes to identify and control pathogens;
- (10) address common and emerging zoonotic diseases;
- (11) develop methods to reduce or destroy harmful pathogens before, during, and after processing:
- (12) analyze the incidence of antibiotic resistance as it pertains to the food supply and develop new methods to reduce infection by antibiotic resistant bacteria in humans and animals: and
- $\left( 13\right)$  conduct other research that supports the purposes of this Act.
- (b) CONTRACT AUTHORITY.—The Administrator may enter into contracts and agreements with any State, institution of higher

education, Federal Government agency, or person to carry out this section.

#### TITLE IV—ENFORCEMENT

#### SEC. 401. PROHIBITED ACTS.

It shall be unlawful—

- (1) for a person-
- (A) to manufacture, introduce, deliver for introduction, or receive into interstate commerce any food that is adulterated, misbranded, or otherwise unsafe;
- (B) to adulterate or misbrand any food in interstate commerce;
- (C) to refuse to permit access to a food facility for the inspection and copying of a record as required under section 205(g):
- (D) to fail to establish or maintain any record or to make any report as required under section 205(g):
- (E) to refuse to permit entry to or inspection of a food facility as required under section 205:
- (F) to fail to provide to the Administrator the results of a testing or sampling of a food, equipment, or material in contact with contaminated food under section 205(g)(1)(B):
- (G) to fail to comply with an applicable provision of, or a regulation or order of the Administrator under, section 202, 204, or 208;
- (H) to slaughter an animal that is capable for use in whole or in part as human food at a food facility processing any such food for commerce, except in compliance with the food safety law;
- (I) to fail to comply with a recall or other order under section 402; or
- (J) to otherwise violate the food safety law; and
- (2) for a food facility or foreign food facility to fail to register under section 202, or to operate without a valid registration.

### SEC. 402. MANDATORY RECALL AUTHORITY.

- (a) VOLUNTARY PROCEDURES.—If the Administrator determines that there is a reasonable probability that an article of food (other than infant formula) is adulterated or misbranded and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Administrator shall provide to the owner, operator, or agent in charge of the facility that created, caused, or was otherwise responsible for that article of food an opportunity to cease distribution and recall that article of food in a manner and within a time period determined by the Administrator.

  (b) PREHEARING ORDER TO CEASE DISTRIBU-
- (b) Prehearing Order To Cease Distribu-TION AND GIVE NOTICE.—
- (1) IN GENERAL.—If the owner, operator, or agent in charge of a facility refuses to, or does not voluntarily, cease distribution or recall an article of food in the manner and within the time period determined by the Administrator under subsection (a), the Administrator may by order require, as the Administrator determines to be necessary—
  - (A) that owner, operator, or agent-
- (i) to immediately cease distribution of that article of food; and
- (ii) as applicable, to immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling that article of food; and
- (B) any person to which that article of food has been distributed, transported, or sold, to immediately cease distribution of that article of food.
  - (2) REQUIRED ADDITIONAL INFORMATION.—
- (A) IN GENERAL.—If an article of food covered by a recall order issued under paragraph (1) has been distributed to a warehouse-based, third-party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order that is in its possession, the notice provided by the owner, operator, or

- agent of a facility under paragraph (1)(A)(ii) shall include such information as is necessary for the warehouse-based, third-party logistics provider to identify the article of food.
- (B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—
- (i) to exempt a warehouse-based, thirdparty logistics provider from the requirements of food safety law; or
- (ii) to exempt a warehouse-based, thirdparty logistics provider from being the subject of a mandatory recall order.
- (3) DETERMINATION TO LIMIT AREAS AF-FECTED.—If the Administrator requires an owner, operator, or agent in charge of the facility to cease distribution under paragraph (1)(A)(i) of an article of food identified under subsection (a), the Administrator may limit the size of the geographic area and the markets affected by such cessation if such limitation would not compromise the public health.
- (c) HEARING ON ORDER.—The Administrator shall provide the owner, operator, or agent in charge of the facility subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled.
- (d) Post-Hearing Recall Order and Modification of Order.—
- (1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Administrator determines that removal of the applicable article of food from commerce is necessary, the Administrator shall, as appropriate—
- (A) amend the order to require recall of such article or other appropriate action;
- (B) specify a timetable in which the recall shall occur:
- (C) require periodic reports to the Administrator describing the progress of the recall; and
- (D) provide notice to consumers to whom such article was, or may have been, distributed
- (2) VACATING OF ORDER.—If, after an informal hearing under subsection (c), the Administrator determines that adequate grounds do not exist to continue the actions required by the applicable order, or that such actions should be modified, the Administrator shall vacate the order or modify the order, as appropriate.
- (e) RULE REGARDING ALCOHOLIC BEVERAGES.—The Administrator shall not initiate a mandatory recall or take any other action under this section with respect to any alcohol beverage until the Administrator has provided the Administrator of the Alcohol and Tobacco Tax and Trade Bureau with a reasonable opportunity to cease distribution and recall the alcohol beverage under the authority of the Administrator of the Alcohol and Tobacco Tax and Trade Bureau.
- (f) COOPERATION AND CONSULTATION.—The Administrator shall work with State and local public health officials in carrying out this section, as appropriate.
- (g) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Administrator shall—
- (1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification—
- (A) of the recall to consumers and retailers to whom the applicable article of food was, or may have been, distributed; and
- (B) that includes, at a minimum-
- (i) the name of the article of food subject to the recall;
- (ii) a description of the risk associated with such article; and

- (iii) to the extent practicable, information for consumers about similar articles of food that are not affected by the recall;
- (2) provide to the public a list of retail consignees receiving products for which there is determined to be a reasonable probability that eating the food will cause serious adverse health consequences or death to humans or animals; and
- (3) if available, publish on the Internet website of the Administration an image of the article that is the subject of the press release described in paragraph (1).
- (h) No DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Administrator.
- (i) EFFECT.—Nothing in this section shall affect the authority of the Administrator to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of the food safety law or under the Public Health Service Act (42 U.S.C. 201 et seq.).
  - (j) COORDINATED COMMUNICATION.—
- (1) In general.—To assist in carrying out the requirements of this subsection, the Administrator shall establish an incident command operation or a similar operation that will operate not later than 24 hours after the initiation of a mandatory recall or the recall of an article of food for which the use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals.
- (2) REQUIREMENTS.—To reduce the potential for miscommunication during recalls or regarding investigations of a foodborne illness outbreak associated with a food that is subject to a recall, each incident command operation or similar operation under paragraph (1) shall use regular staff and resources of the Administration to—
- (A) ensure timely and coordinated communication within the Administration, including enhanced communication and coordination between different agencies and organizations within the Administration;
- (B) ensure timely and coordinated communication from the Administration, including public statements, throughout the duration of the investigation and related foodborne illness outbreak:
- (C) identify a single point of contact within the Administration for public inquiries regarding any actions by the Administrator related to a recall:
- (D) coordinate with Federal, State, local, and Tribal authorities, as appropriate, that have responsibilities related to the recall of a food or a foodborne illness outbreak associated with a food that is subject to the recall, including notification of the Secretary of Agriculture and the Secretary of Education in the event such recalled food is a commodity intended for use in a child nutrition program (as defined in section 25(b) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769f(b))); and
- (E) conclude operations at such time as the Administrator determines appropriate.
- (3) MULTIPLE RECALLS.—The Administrator may establish multiple or concurrent incident command operations or similar operations in the event of multiple recalls or foodborne illness outbreaks.
- (4) FEES APPLICABLE TO ALL FACILITIES.—Fees described in section 743 of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–31) for not complying with a recall order are applicable to all food facilities under this Act as if—
- (A) the term "responsible party" means "owner, operator, or agent in charge of the facility"; and

(B) references to section 423 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350*l*) are references to section 402 of this Act.

#### SEC. 403. INJUNCTION PROCEEDINGS.

- (a) JURISDICTION.—The district courts of the United States, and the United States courts of the territories and possessions of the United States, shall have jurisdiction, for cause shown, to restrain a violation of section 202, 203, 204, 207, or 401 (or a regulation promulgated under that section).
- (b) TRIAL.—In a case in which violation of an injunction or restraining order issued under this section also constitutes a violation of the food safety law, trial shall be by the court or, upon demand of the accused, by a jury.

### SEC. 404. CIVIL AND CRIMINAL PENALTIES.

- (a) CIVIL SANCTIONS.—
- (1) CIVIL PENALTY.—
- (A) IN GENERAL.—Any person that violates section 401 may be assessed a civil penalty by the Administrator of not more than \$250,000 for each violation.
- (B) SEPARATE OFFENSE.—Each violation described in subparagraph (A) and each day during which that violation continues shall be considered a separate offense.
- (2) OTHER REQUIREMENTS.—
- (A) WRITTEN ORDER.—The civil penalty described in paragraph (1) shall be assessed by the Administrator by a written order, which shall specify the amount of the penalty and the basis for the penalty under subparagraph (B) considered by the Administrator.
- (B) AMOUNT OF PENALTY.—Subject to paragraph (1)(A), the amount of the civil penalty shall be determined by the Administrator, after considering—
  - (i) the gravity of the violation:
- (ii) the degree of culpability of the person; (iii) the size and type of the business of the person; and
- (iv) any history of prior offenses by the person under the food safety law.
- (C) REVIEW OF ORDER.—A written order under subparagraph (A) may be reviewed only in accordance with subsection (c).
  - (b) CRIMINAL SANCTIONS.—
- (1) IN GENERAL.—Except as provided in paragraphs (2) and (3), a person that violates subparagraph (A) or (B) of section 401(1) shall be imprisoned for not more than 1 year, fined not more than \$10,000 or both
- (2) SEVERE VIOLATIONS.—A person that commits a violation described in paragraph (1) after a conviction of that person under this section has become final, or commits such a violation with the intent to defraud or mislead, shall be imprisoned for not more than 3 years, fined not more than \$100,000, or both
- (3) EXCEPTION.—No person shall be subject to the penalties of this subsection—  $\,$
- (A) for having received, proffered, or delivered in interstate commerce any food, if the receipt, proffer, or delivery was made in good faith, unless that person refuses to furnish (on request of an officer or employee designated by the Administrator)—
- (i) the name, address, and contact information of the person from whom that person purchased or received the food;
- (ii) copies of all documents relating to the person from whom that person purchased or received the food; and
- (iii) copies of all documents pertaining to the delivery of the food to that person; or
- (B) if that person establishes a guaranty signed by, and containing the name and address of, the person from whom that person received in good faith the food, stating that the food is not adulterated or misbranded within the meaning of this Act.
  - (c) JUDICIAL REVIEW.-
- (1) IN GENERAL.—An order assessing a civil penalty under subsection (a) shall be a final order unless the person—

- (A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—
- (i) the court of appeals of the United States for the judicial circuit in which that person resides or has its principal place of business; or
- (ii) the United States Court of Appeals for the District of Columbia Circuit; and
- (B) simultaneously serves a copy of the petition by certified mail to the Administrator.
- (2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Administrator shall file in the court a certified copy of the administrative record upon which the order was issued.
- (3) STANDARD OF REVIEW.—The findings of the Administrator relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.
- (d) Collection Actions for Failure To Pay.—
- (1) In GENERAL.—If any person fails to pay a civil penalty assessed under subsection (a) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (c) has entered final judgment in favor of the Administrator, the Administrator shall refer the matter to the Attorney General, who shall institute in a district court of the United States of competent jurisdiction a civil action to recover the amount assessed.
- (2) LIMITATION ON REVIEW.—In a civil action under paragraph (1), the validity and appropriateness of the order of the Administrator assessing the civil penalty shall not be subject to judicial review.
- (e) PENALTIES PAID INTO ACCOUNT.—The Administrator—
- (1) shall deposit penalties collected under this section in an account in the Treasury; and
- (2) may use the funds in the account, without further appropriation or fiscal year limitation—
- (A) to carry out enforcement activities under food safety law; or
- (B) to provide assistance to States to inspect retail commercial food establishments or other food or firms under the jurisdiction of State food safety programs
- of State food safety programs.

  (f) DISCRETION OF THE ADMINISTRATOR TO PROSECUTE.—Nothing in this Act requires the Administrator to report for prosecution, or for the commencement of an action, the violation of the food safety law in a case in which the Administrator finds that the public interest will be adequately served by the assessment of a civil penalty under this section.
- (g) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section may be in addition to, and not exclusive of, other remedies that may be available.

#### SEC. 405. PRESUMPTION.

In any action to enforce the requirements of the food safety law, the connection with interstate commerce required for jurisdiction shall be presumed to exist.

### SEC. 406. WHISTLEBLOWER PROTECTION.

Section 1013 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399d) shall apply with respect to any violation of, or any act or omission an employee reasonably believes to be a violation of, any provision of this Act to the same extent and in the same manner as that section applies with respect to a violation of, or any act or omission an employee reasonably believes to be a violation of, any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

### SEC. 407. ADMINISTRATION AND ENFORCEMENT.

(a) IN GENERAL.—For the efficient administration and enforcement of the food safety

law, the provisions (including provisions relating to penalties) of sections 6, 8, 9, and 10 of the Federal Trade Commission Act (15 U.S.C. 46, 48, 49, and 50) (except subsections (c) through (h) of section 6 of that Act (15 U.S.C. 46)), relating to the jurisdiction, powers, and duties of the Federal Trade Commission and the Attorney General to administer and enforce that Act, and to the rights and duties of persons with respect to whom the powers are exercised, shall apply to the jurisdiction, powers, and duties of the Administrator and the Attorney General in administering and enforcing the provisions of the food safety law and to the rights and duties of persons with respect to whom the powers are exercised, respectively.

(b) INQUIRIES AND ACTIONS.—

(1) IN GENERAL.—The Administrator, in person or by such agents as the Administrator may designate, may prosecute any inquiry necessary to carry out the duties of the Administrator under the food safety law in any part of the United States.

(2) POWERS.—The powers conferred by sections 9 and 10 of the Federal Trade Commission Act (15 U.S.C. 49, 50) on the United States district courts may be exercised for the purposes of this chapter by any district court of the United States of competent jurisdiction.

#### SEC. 408. CITIZEN CIVIL ACTIONS.

- (a) CIVIL ACTIONS.—A person may commence a civil action against—
- (1) a person that violates a regulation (including a regulation establishing a performance standard), order, or other action of the Administrator to ensure the safety of food;
- (2) the Administrator (in his or her capacity as the Administrator), if the Administrator fails to perform an act or duty to ensure the safety of food that is not discretionary under the food safety law.
  - (b) COURT.-
- (1) IN GENERAL.—The action shall be commenced in the district court of the United States for the judicial district in which the defendant resides, is found, or has an agent.
- (2) JURISDICTION.—The court described in paragraph (1) shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce a regulation (including a regulation establishing a performance standard), order, or other action of the Administrator, or to order the Administrator to perform the act or duty.
- (3) DAMAGES.—The court described in paragraph (1) may—
- (A) award damages, in the amount of damages actually sustained; and
- (B) if the court determines it to be in the interest of justice, award the plaintiff the costs of suit, including reasonable attorney's fees, reasonable expert witness fees, and penalties.
- (c) REMEDIES NOT EXCLUSIVE.—The remedies provided for in this section shall be in addition to, and not exclusive of, other remedies that may be available.

## TITLE V—IMPLEMENTATION

## SEC. 501. DEFINITION.

In this title, the term "transition period" means the 12-month period beginning on the date of enactment of this Act.

### SEC. 502. REORGANIZATION PLAN.

- (a) SUBMISSION OF PLAN.—Not later than 180 days after the date of enactment of this Act, the President shall transmit to the appropriate congressional committees a reorganization plan regarding the following:
- (1) The transfer of agencies, personnel, assets, and obligations to the Administration pursuant to this Act.
- (2) Any consolidation, reorganization, or streamlining of agencies transferred to the Administration pursuant to this Act.

- (b) PLAN ELEMENTS.—The plan transmitted under subsection (a) shall contain, consistent with this Act, such elements as the President determines appropriate, including the following:
- (1) Identification of any functions of agencies designated to be transferred to the Administration pursuant to this Act that will not be transferred to the Administration under the plan.
- (2) Specification of the steps to be taken by the Administrator to organize the Administration, including the delegation or assignment of functions transferred to the Administration among the officers of the Administration in order to permit the Administration to carry out the functions transferred under the plan.
- (3) Specification of the funds available to each agency that will be transferred to the Administration as a result of transfers under the plan.
- (4) Specification of the proposed allocations within the Administration of unexpended funds transferred in connection with transfers under the plan.
- (5) Specification of any proposed disposition of property, facilities, contracts, records, and other assets and obligations of agencies transferred under the plan.
- (6) Specification of the proposed allocations within the Administration of the functions of the agencies and subdivisions that are not related directly to ensuring the safety of food.
- (c) Modification of Plan.—The President may, on the basis of consultations with the appropriate congressional committees, modify or revise any part of the plan until that part of the plan becomes effective in accordance with subsection (d).
  - (d) EFFECTIVE DATE.—
- (1) IN GENERAL.—The reorganization plan described in this section, including any modifications or revisions of the plan under subsection (c), shall become effective for an agency on the earlier of—
- (A) the date specified in the plan (or the plan as modified pursuant to subsection (c)), except that such date may not be earlier than 90 days after the date the President has transmitted the reorganization plan to the appropriate congressional committees pursuant to subsection (a); or
  - (B) the end of the transition period.
- (2) STATUTORY CONSTRUCTION.—Nothing in this subsection may be construed to require the transfer of functions, personnel, records, balances of appropriations, or other assets of an agency on a single date.
- (3) SUPERCEDES EXISTING LAW.—Paragraph (1) shall apply notwithstanding section 905(b) of title 5. United States Code.

## SEC. 503. TRANSITIONAL AUTHORITIES.

- (a) Provision of Assistance by Officials.—Until the transfer of an agency to the Administration, any official having authority over or function relating to the agency on the day before the date of enactment of this Act shall provide the Administrator such assistance, including the use of personnel and assets, as the Administrator may request in preparing for the transfer and integration of the agency to the Administration.
- (b) SERVICES AND PERSONNEL.—During the transition period, upon the request of the Administrator, the head of any Executive agency may, on a reimbursable basis, provide services or detail personnel to assist with the transition.
  - (c) ACTING OFFICIALS.—
- (1) IN GENERAL.—During the transition period, pending the advice and consent of the Senate to the appointment of an officer required by this Act to be appointed by and with such advice and consent, the President

- may designate any officer whose appointment was required to be made by and with such advice and consent and who was such an officer on the day before the date of enactment of this Act (and who continues to be in office) or immediately before such designation, to act in such office until the same is filled as provided in this Act.
- (2) COMPENSATION.—While acting pursuant to paragraph (1), such officers shall receive compensation at the higher of—
- (A) the rates provided by this Act for the respective offices in which they act; or
- (B) the rates provided for the offices held at the time of designation.
- (3) LIMITATION.—Nothing in this Act shall be construed to require the advice and consent of the Senate to the appointment by the President to a position in the Administration of any officer whose agency is transferred to the Administration pursuant to this Act and whose duties following such transfer are germane to those performed before such transfer.
- (d) Transfer of Personnel, Assets, Obligations, and Function.—
- (1) IN GENERAL.—Consistent with section 1531 of title 31, United States Code, the personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds that relate to the functions transferred under subsection (a) from a Federal agency shall be transferred to the Administration.
- (2) UNEXPENDED FUNDS.—Unexpended funds transferred under this subsection shall be used by the Administration only for the purposes for which the funds were originally authorized and appropriated.

#### SEC. 504. SAVINGS PROVISIONS.

- (a) COMPLETED ADMINISTRATIVE ACTIONS.— The enactment of this Act or the transfer of functions under this Act shall not affect any order, determination, rule, regulation, permit, personnel action, agreement, grant, contract, certificate, license, registration, privilege, or other administrative action issued, made, granted, or otherwise in effect or final with respect to that agency on the day before the transfer date with respect to the transferred functions.
- (b) PENDING PROCEEDINGS.—Subject to the authority of the Administrator under this Act—
- (1) pending proceedings in an agency, including notices of proposed rulemaking, and applications for licenses, permits, certificates, grants, and financial assistance, shall continue notwithstanding the enactment of this Act or the transfer of the agency to the Administration, unless discontinued or modified under the same terms and conditions and to the same extent that such discontinuance could have occurred if such enactment or transfer had not occurred; and
- (2) orders issued in such proceedings, and appeals from those orders, and payments made pursuant to such orders, shall be issued in the same manner on the same terms as if this Act had not been enacted or the agency had not been transferred, and any such order shall continue in effect until amended, modified, superceded, terminated, set aside, or revoked by an officer of the United States or a court of competent jurisdiction, or by operation of law.
- (c) PENDING CIVIL ACTIONS.—Subject to the authority of the Administrator under this Act, any civil action commenced with regard to that agency pending before that agency on the day before the transfer date with respect to the transferred functions shall continue notwithstanding the enactment of this Act or the transfer of an agency to the Administration.
  - (d) References.—

- (1) IN GENERAL.—After the transfer of functions from a Federal agency under this Act, any reference in any other Federal law, Executive order, rule, regulation, directive, document, or other material to that Federal agency or the head of that agency in connection with the administration or enforcement of the food safety laws shall be deemed to be a reference to the Administration or the Administrator, respectively.
- (2) STATUTORY REPORTING REQUIREMENTS.— Statutory reporting requirements that applied in relation to such an agency on the day before the date of enactment of this Act shall continue to apply following such transfer if the reporting requirements refer to the agency by name.

#### SEC. 505. CONFORMING AMENDMENTS.

Section 5313 of title 5, United States Code, is amended by adding at the end the following new item:

"Administrator of Food Safety.".

# SEC. 506. ADDITIONAL TECHNICAL AND CONFORMING AMENDMENTS.

Not later than 60 days after the submission of the reorganization plan under section 502, the President shall prepare and submit proposed legislation to Congress containing necessary and appropriate technical and conforming amendments to any food safety law to reflect the changes made by this Act.

#### SEC. 507. REGULATIONS.

The Administrator may promulgate such regulations as the Administrator determines are necessary or appropriate to perform the duties of the Administrator.

### SEC. 508. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this Act.

#### SEC. 509. LIMITATION ON AUTHORIZATION OF AP-PROPRIATIONS.

For the fiscal year that includes the date of enactment of this Act, the amount authorized to be appropriated to carry out this Act shall not exceed—

- (1) the amount appropriated for that fiscal year for the Federal agencies identified in section 102(b) for the purpose of administering or enforcing the food safety law; or
- (2) the amount appropriated for those agencies for that purpose for the preceding fiscal year, if, as of the date of enactment of this Act, appropriations for those agencies for the fiscal year that includes that date of enactment have not yet been made.

# By Mr. WYDEN (for himself and Mr. MERKLEY):

S. 1997. A bill to authorize transitional sheltering assistance for individuals who live in areas with unhealthy air quality caused by wildfires, and for other purposes; to the Committee on Homeland Security and Governmental Affairs.

Mr. WYDEN. Mr. President, today I am introducing the Wildfire Smoke Relief Act of 2019 with the ultimate goal of providing Federal emergency assistance to at risk individuals in areas with unhealthy air quality caused by wildfire smoke. By actively preparing for the effects of wildfire smoke inhalation, this bill attempts to ensure the long term health and security of all of those affected by wildfires

In 2018, over 2,000 fires burned nearly 900,000 acres in the State of Oregon. The result of these fires was weeks and weeks of wildfire smoke. In Southern Oregon alone, there were 39 days with unhealthy air quality directly caused by smoke from wildfires. People need

proper air filtration equipment, and in extreme cases, to seek refuge in a smokeless area. Communities are being choked by wildfire smoke, and each year wildfires are becoming more destructive than the previous.

Vulnerable populations like children, the elderly, pregnant women, and lowincome families are disproportionately affected by wildfire smoke. Additionally, those with chronic heart or lung conditions are at a similarly heightened risk. Symptoms from smoke inhalation can develop within a relatively short time of exposure, and according to research, is akin to smoking several packs of cigarettes per day. Symptoms vary and can include poor development of lungs in children, shortness of breath, coughing, chest pain, nausea, reduced lung capacity, bronchitis, headaches, and visual impairment.

The bill would authorize the Federal Emergency Management Agency (FEMA) to provide assistance to at risk individuals by providing smoke inhalation prevention equipment and lowcost home improvements when air quality causes unhealthy air quality levels or three consecutive days. Smoke inhalation prevention equipment would include an air filter, a face mask or respirator, a portable air filtration unit, and other low cost equipment used to keep smoke out of a house

In severe cases, the Wildfire Smoke Relief Act would authorize FEMA to provide transitional sheltering assistance for at risk individuals. In these extreme cases FEMA can arrange alternate, cost-efficient housing arranged for at-risk people to escape the smoke.

Mr. President, I am pleased to be joined by Senator JEFF MERKLEY in introducing the bill today and look forward to working with my colleagues toward enactment of the Wildfire Smoke Relief Act in the 116th Congress.

#### SUBMITTED RESOLUTIONS

SENATE RESOLUTION 265—DESIGNATING JULY 27, 2019, AS "NATIONAL DAY OF THE AMERICAN COWBOY"

Mr. ENZI (for himself, Ms. CORTEZ MASTO, Mr. RISCH, Mr. THUNE, Mr. TESTER, Mr. MERKLEY, Mr. BARRASSO, Mr. CRAPO, Mr. HOEVEN, Mr. ROUNDS, Mr. BENNET, Mr. UDALL, Mr. INHOFE, and Mr. CORNYN) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 265

Whereas pioneering men and women, recognized as "cowboys", helped to establish the American West;

Whereas the cowboy embodies honesty, integrity, courage, compassion, respect, a strong work ethic, and patriotism;

Whereas the cowboy spirit exemplifies strength of character, sound family values, and good common sense;

Whereas the cowboy archetype transcends ethnicity, gender, geographic boundaries, and political affiliations;

Whereas the cowboy, who lives off the land and works to protect and enhance the environment, is an excellent steward of the land and its creatures;

Whereas cowboy traditions have been a part of American culture for generations;

Whereas the cowboy continues to be an important part of the economy through the work of many thousands of ranchers across the United States who contribute to the economic well-being of every State;

Whereas millions of fans watch professional and working ranch rodeo events annually, making rodeo one of the most-watched sports in the United States;

Whereas membership and participation in rodeo and other organizations that promote and encompass the livelihood of cowboys span every generation and transcend race and gender;

Whereas the cowboy is a central figure in literature, film, and music and occupies a central place in the public imagination:

Whereas the cowboy is an American icon; and

Whereas the ongoing contributions made by cowboys and cowgirls to their communities should be recognized and encouraged: Now, therefore, be it

Resolved, That the Senate-

- (1) designates July 27, 2019, as "National Day of the American Cowboy"; and
- (2) encourages the people of the United States to observe the day with appropriate ceremonies and activities.

SENATE RESOLUTION 266—CON-GRATULATING THE ST. LOUIS BLUES FOR WINNING THE 2019 STANLEY CUP FINAL

Mr. HAWLEY (for himself and Mr. BLUNT) submitted the following resolution; which was considered and agreed to:

## S. RES. 266

Whereas, on June 12, 2019, the St. Louis Blues won the 2019 Stanley Cup Final;

Whereas the Blues, in their 52nd year playing in the National Hockey League (referred to in this preamble as the "NHL"), made their fourth Stanley Cup Final appearance, and their first since the 1969–70 season;

Whereas the Blues defeated the 2019 Eastern Conference champions, the Boston Bruins, in the Stanley Cup Final to win their first Stanley Cup, clinching the series with 4 wins and 3 losses;

Whereas the Blues defeated the Winnipeg Jets, the Dallas Stars, and the San Jose Sharks to earn the Western Conference title and win the franchise's third Clarence S. Campbell Bowl;

Whereas the Blues showed incredible determination and perseverance by fighting their way back from last place in the NHL on January 3, 2019, to finish the regular season in third place in the Western Conference Central Division, and to eventually defeat the Boston Bruins to become Stanley Cup Champions;

Whereas the City of St. Louis was named by the Wall Street Journal as the best sports city in the United States in 2015, highlighting the success of St. Louis professional sports teams;

Whereas more than 10,000 fans filled the Enterprise Center, more than 20,000 fans filled Busch Stadium in the pouring rain, and more than 18,000 fans flooded downtown St. Louis to cheer the Blues on to the franchise's first Stanley Cup;

Whereas the Blues and the City of St. Louis embraced Laura Branigan's 1982 hit song, "Gloria", uniting fans across the country: